ZENECA Pharmaceuticals
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ZENECA

SENT VIA UPS NEXT DAY AIR

APR 1 9 1999

Dockets Management Branch
Food and Drug Administration
HFA No. 305, Room No. 1061
5630 Fishers Lane
Rockville, MD 20857

Dear Madam/Sir:

Re: Docket No. 77N-0240
Certain Single-Entity Coronary Vasodilators Containing Isosorbide Dinitrate;
Opportunity for a Hearing
Written Notice of Appearance and Request for Hearing

Reference is made to the Notice published in the Federal Register on March 22, 1999 (64 FR 13802) in which the FDA proposed to withdraw approval of 25 Abbreviated New Drug Applications (ANDAs) for certain single-entity coronary vasodilator drug products containing isosorbide dinitrate. In the Notice, the FDA further offered the holders of those applications listed in the Notice an opportunity for a hearing on the proposal to withdraw the ANDAs.

Accordingly, Zeneca hereby enters its appearance and requests that the FDA grant Zeneca a hearing in the above-captioned matter with respect to its ANDA 86-388 for SORBITRATE® (isosorbide dinitrate) Chewable Tablets 10 mg, and ANDA 88-074 for SORBITRATE® (isosorbide dinitrate) Oral Tablets 20 mg for Export. Zeneca will file by May 21, 1999 the data, information, and analyses relied on to justify a hearing with respect to ANDA 86-388 and ANDA 88-074.

77N-0240

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Please contact me if you have any questions or require further information.

Sincerely,

William J. Kennedy, Ph.D.
Vice President
Drug Regulatory Affairs Department
(302) 886-2132
(302) 886-2822 (fax)

WJK/RJO/jr